**FDA MEDICAL EQUIPMENT RECALLS AND ALERTS**. The following recalls are reported in Accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items.
**(FOM-P, Capt Paul J. Toth, DSN 343-7445)**

**CLASS I RECALLS: None**

**CLASS II RECALLS:**

**6515 NS**

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|---|---|
| **MDC 10134, 10144, 10145, 97001** | **Anesthesia Units (General)** |
| PRODUCT | Datex-Ohmeda AS/3 Anesthesia Delivery Unit (ADU), a complete anesthesia delivery unit with electronically controlled ventilator, gas delivery and agent vaporizing units. Recall #Z-004-1. |
| CODE | Serial Numbers: 40022203 and above. |
| MANUFACTURER | Datex-OHMEDA, Inc., Tewksbury, Massachusetts. |
| RECALLED BY | Manufacturer, by voice mail on April 28, 2000, followed by visit beginning May 5, 2000. Firm-initiated field correction ongoing. |
| DISRIBUTION | Nationwide and international. |
| QUANTITY | 1,150 units were distributed. |
| REASON | The device has reliability problems with fresh gas delivery, agent delivery and ventilation functions. |

[ ] None Present
[ ] Action Taken _____
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**6530 NS**

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|---|---|
| **MDC 16214** | **Wheelchairs, Powered** |
| PRODUCT | Power Chairs: a) Rascal Model Numbers RAS 545 and RAS 445; b) Chauffeur Model Numbers: P48, S45, X48, and X48E. Recall #Z-1029/1030-0. |
| CODE | Identified power chairs are: PC004492, PC004493, PC004494, PC004501, PC004502, PC004508, PC004511, PC004527, PC004532, PC004534, PC004536, PC004552, PC004553, PC004555, PC004556, PC004579, JS004709. |
| MANUFACTURER | Electric Mobility Corporation, Sewell, New Jersey. |
| RECALLED BY | Manufacturer, by letter August 11, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | a) North Carolina, Indiana, Florida, Pennsylvania, New York, Kentucky, California, Kansas, Mississippi, and West Virginia, England; b) Alabama. |
| QUANTITY | 17 chairs were distributed. |
| REASON | The Power chairs' controller program does not meet the original engineering specifications. |

[ ] None Present
[ ] Action Taken _____
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**6630 NS**

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|---|---|
| **MDC 16405** | **Apheresis Unit** |
| PRODUCT | Fenwal Autopheresis-C Plasmapheresis System, Models A-200, A-201, and A-401. Recall #B-860-0. |
| CODE | Product Code Numbers: 4R4550, 4R4560, 4R4561, R4R4585 |
| MANUFACTURER | Baxter Healthcare Corporation, Largo, Florida. |
| SOFTWARE DEVELOPER | Baxter Healthcare Corporation, Round Lake, Illinois. |
| RECALLED BY | Baxter Healthcare Corporation, Deerfield, Illinois, by telephone and fax dated May 5, 2000, followed by letter dated June 15, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nationwide and Canada. |
| QUANTITY | 5,250 units were distributed |
| REASON | The Autopheresis-C Plasmapheresis instruments with version 6.0 software may proceed to "Saline Rinse" without displaying the “Remove Plasma” prompt. |

[ ] None Present
[ ] Action Taken _____
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**CLASS II RECALLS:**

**6630 NS**

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|---|---|
| **MDC 16817** | **Blood Grouping Systems, Automated** |
| PRODUCT | PK7100 and PK7200 CMV-PA Automated Blood Grouping Analyzer CMV Test System and Controls:<br>Olympus PK7100 Automated Blood Grouping System, Product Code 81KSZ;<br>Olympus PK7200 Automated Microplate System, Product Code 81KSZ;<br>Olympus PK CMV-PA Cytomegalovirus serological reagents, Product Code MZE. Recall #B-1295-0. |
| CODE | All lot and serial numbers are affected. |
| MANUFACTURER | PK7100 & PK7200 Automated Analyzer: Olympus Optical Co., Ltd., Tokyo, Japan PK CMV-PA Systems and Controls: Fujirebio America, Inc., Fairfield, New Jersey; Fujirebio, Inc., Tokyo, Japan;<br>SCIMEDIX Corp., Denville, New Jersey. |
| RECALLED BY | Olympus America, Inc., Irving, Texas (distributor), by letter dated July 17, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | North Carolina, California, Louisiana, Florida, Kentucky, Virginia, Illinois, Tennessee, Oklahoma, Canada. |
| QUANTITY | PK7100: 2 analyzers; PK7200 38 analyzers were distributed. 412,000 tests per month were distributed. |
| REASON | Automated test systems, which may have produced incorrect CMV antibody test results. |

[ ] None Present
[ ] Action Taken _____
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**2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION**. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

**CLASS I:** A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

**CLASS II:** A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**CLASS III:** A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. **CONUS** activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. **OVERSEAS** activities will report quantities suspended to AFMLO/FOM-P no later than **05JAN 01** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP purchase order number, contract number, and stock record account number (SRAN). (FOM-P**), Bonnie Phillips DSN (343-4170)**

**CLASS I RECALLS: None**

**CLASS II RECALLS:**

| | |
|---|---|
| NSN | 6505 Nonstandard |
| PRODUCT | Source Leukocytes. Recall #B-1085-0. |
| CODE | Unit #3600010. |
| MANUFACTURER | Gulf Coast Regional Blood Center, Houston, Texas. |
| RECALLED BY | Manufacturer, by fax on May 5, 1999, and August 22 and 30, 1999. Firm-initiated recall ongoing. |
| DISTRIBUTION | Pennsylvania. |
| QUANTITY | 1 unit was distributed. |
| REASON | Blood product was collected from a donor who had previously been deferred for high risk behavior. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6515 Nonstandard |
| PRODUCT | Centrex Bipolar Endoprothesis Comp, used in comjunction with a femoral stem component in the reconstruction of a femoral head damaged by fresh fracture non-union aseptic necrosis of the femoral head and neck or by osteoarthritis or post-traumatic arthritis. Recall #Z-963-0. |
| CODE | Catalog No. 6225-2-846, Lot Code GOUDA. |
| MANUFACTURER | Howmedica Osteonics Corporation, Rutherford, New Jersey. |
| RECALLED BY | Manufacturer, by letter dated June 22, 2000. Firm-initiated recall ongoing. |

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|---|---|
| DISTRIBUTION | Nationwide, Australia and Canada. |
| QUANTITY | 11 units were distributed. |
| REASON | A 26mm UHWPE insert was issued instead of a 28mm insert. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6550 Nonstandard |
| PRODUCT | Isoniazid drug lot No. 9335260 used in the following kits:<br>BACTEC(tm) S.I.R.E. Drug Kit used for susceptibility testing of Mycobacterium tuberculosis, Catalog No. 442102, Lot Nos. 9327296, 93442298, 9327298;<br>BACTEC(tm) Isoniazid Drug Kit used for isoniazid susceptibility testing, Catalog No. 442146, Lot No. 9327297. Recall #Z-1032-0. |
| CODE | See above. |
| MANUFACTURER | Becton Dickinson Microbiology Systems, Cockeysville, Maryland. |
| RECALLED BY | Becton Dickinson Microbiology Systems, Sparks, Maryland, by letter on August 22 and 25, 2000, followed by telephone on September 6, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nationwide, Hong Kong, Philippines, Australia, Brazil, New Delhi, Singapore, Puerto Rico, Belgium, Canada, Argentina. |
| QUANTITY | 148 Isoniazid Drug Kits and 490 S.I.R.E. Kits were distributed. |
| REASON | Some bottles of the products listed above are labeled Isoniazid but actually contain Streptomycin. |

[ ] None Present
[ ] Action Taken _____
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**CLASS III RECALLS:**

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|---|---|
| NSN | 6505 Nonstandard |
| PRODUCT | BC(r) brand Headache Powder (650 mg Aspirin, 195 mg Salicylamide, 33.3 Caffeine), packaged in 2's NDC# 1015800908, packaged in 6's NDC# 1015800910,packaged in 24's NDC# 1015800912, packaged in 50's NDC# 1015800916. Recall#D-457-0. |
| CODE | Lot Numbers:<br>M000580, M000581, M000582, M000583, M000857, M000858, M000859, M000860,<br>M000861, M000862, M000863, M000864, M000865, M000866, M001703, M001704,<br>M001705, M001706, M001707, M001708, M001709, M001710, M001711, M001712,<br>M002205, M002206, M002207, M002208, M002209, M002210, M002211, M002212,<br>M002213, M002214, M002771, M002772, M002773, M002774, M002780, M002903,<br>M002904, M002905, M002906, M002907, M002908, M002909, M002910, M002911, |

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|---|---|
| | M002912, M003265, M003390, M003391, M003392, M003393, M003394, M003395,<br>M003396, M003397, M003398, M003420, M003428, M003429, M003430, M003431,<br>M003432, M003433, M003434, M003435, M003436, M003437, M004001, M004049,<br>M004050, M004051, M004052, M004053. |
| MANUFACTURER | Block Drug Company, Memphis, Tennessee. |
| RECALLED BY | Block Drug Company, Jersey, City, New Jersey, by letter on May 30, 2000, and June 23, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nationwide. |
| QUANTITY | BC Powder 2"s ---316,714/60dz<br>BC Powder 6's ----180,232/60dz<br>BC Powder 24's ----1,806/3dz<br>BC Powder 50's ----18,188/3dz were distributed. |
| REASON | Discoloring of glassine envelopes holding product. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6505 Nonstandard |
| UPDATE | Jordan's Epinephrine Injection, USP, 1:1000, 1mg/mL, in 1 mL ampuls, which appeared in the May 24, 2000 Enforcement Report should have been listed as follows:<br>Class II -- Recall #D-349-0, Lot Numbers: 980308, 980401, 980501, 980601, 990205; and Class III -- Recall #D-350-0, Lot Numbers: Lot Numbers: 980402, 990307, 990308. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6515 Nonstandard |
| PRODUCT | Replace 4.3mm Conical Abutment, 4.3mm diameter x 4.5 mm height, Catalog #43503. An abutment is used either for single or multiple unit, screw-retained prosthetic restorations. Recall #Z-1025-0. |
| CODE | Lot #308039 EXP 2/05. |
| MANUFACTURER | Nobel Biocare USA, Inc., Yorba Linda, California. |
| RECALLED BY | Manufacturer, by letter on June 13, 2000, followed by telephone. Firm-initiated recall ongoing. |
| DISTRIBUTION | Florida, Illinois, Louisiana, Michigan, Minnesota, North Carolina, New York, Ohio, Pennsylvania, Texas, Hong Kong, Israel, Mexico. |
| QUANTITY | 40 units were distributed. |
| REASON | The conical abutment was not the size as labeled. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6515 Nonstandard |
| PRODUCT | IMC (Intramobile Connector) Conversion Screw, 3.3mm diameter, Catalog #8198CA. An IMC cylinder is used for either single or multiple unit, screw-retained prosthetic restorations. Recall #Z-1026-0. |
| CODE | Lot #310052. |
| MANUFACTURER | Nobel Biocare USA, Inc., Yorba Linda, California. |
| RECALLED BY | Manufacturer, by letter on June 14, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Arizona, Connecticut, Delaware, Florida, Indiana, Massachusetts, Maryland, Michigan, New Jersey, New York, Ohio, Texas. |
| QUANTITY | 29 units were distributed. |
| REASON | The screw in the package is incorrect. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6515 Nonstandard |
| PRODUCT | Replace 4.3mm Conical Abutment, 4.3mm diameter x 1.5mm height, Catalog #43500. An abutment is used either for single or multiple unit, screw-retained prosthetic restorations. Recall Z-1028-0. |
| CODE | Lot #308028 EXP 2/05. |
| MANUFACTURER | Nobel Biocare USA, Inc., Yorba Linda, California. |
| RECALLED BY | Manufacturer, by letter on June 12, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | California, Florida, Idaho, Indiana, New York, Colombia, Hong Kong, Mexico, South Korea. |
| QUANTITY | 41 units were distributed. |
| REASON | The conical abutment was not the size as labeled. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6550 Nonstandard |
| PRODUCT | Vitros Immunodiagnostic Products brand of:<br>Prolactin Reagent Pack, 100 test units per pack<br>Catalog No.184 9793; and associated Vitros Prolactin Calibrators, Catalog No. 111 3596, for in vitro diagnostic use only. Recall #Z-1023/1024-0. |
| CODE | Catalog No. 1849793, Lot No.90, EXP 09/15/2000;<br>Catalog No. 1112595, Lot No.90, EXP 09/15/2000. |
| MANUFACTURER | Ortho-Clinical Diagnostics, Inc., Forest Farm Estate Whitchurch, Cardiff, UK. |
| RECALLED BY | Ortho-Clinical Diagnostics, Inc., Rochester, New York, by letter dated May 24, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Alabama, Arizona, Kansas, Missouri, Virginia, Washington state, Argentina, Australia, Brazil, Canada, Chile, Colombia, India, Japan, Mexico, Puerto Rico, Panama, Singapore, Venezuela, England, France, Germany, Italy, and Spain. |

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| QUANTITY | 764 packs were distributed. |
| REASON | Calibration failures may occur when using this lot of product due to lower than expected light unit output for the level 1 calibrator. |

[ ] None Present
[ ] Action Taken _____
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|---|---|
| NSN | 6550 Nonstandard |
| PRODUCT | ProCide-D Plus Sterilizing & Disinfecting Solution. Recall #Z-1031-0. |
| CODE | Lot #200020002 EXP 7/02 |
| MANUFACTURER | Metrex Research Corporation, Parker, Colorado. |
| RECALLED BY | Sybron Dental Specialties, Inc., Orange, California, letter on August 7, 2000. Firm-initiated recall ongoing. |
| DISTRIBUTION | Alabama, Iowa, Indiana, New York, Oregon, Pennsylvania, West Virginia, Texas. |
| QUANTITY | 280 gallons were distributed. |
| REASON | Part of the subject lot was mislabeled as Procide-D Plus, which contains 3.4% glutaraldehyde, rather Procide-D, which contains 2.5% glutaraldehyde. |

[ ] None Present
[ ] Action Taken _____
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